

REMARKS

Entry of this Amendment is proper under 37 C.F.R. § 1.114, because the Amendment meets the submission requirement. Entry of the Amendment, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.114, are thus respectfully requested.

1. Status of the Claims

Claims 1, 4, 5, 7-21, and 24-32 stand pending. Claims 2-3, 6, and 22-23 stand canceled. Claims 1, 4, 5, 7, 15-18, 21, 24, -27 and 29-32 stand rejected. Claims 8-14, 19-20, and 28 are withdrawn.

After entry of the above amendments, claims 1, 21, and 27 are amended, claims 7 and 25-26 are canceled, and claims 33-35 are added. Thus, claims 1, 4, 5, 8-21, 24, and 27-35 are pending.

2. Support for the Amendments

The amendments and new claims are supported, for example, in at least the original claims and the Specification, for example, at page 7, lines 1-5; page 11, lines 16-25; page 19, line 19 – page 20, line 26; and Examples 27 and 28 starting on page 51.

Thus, no prohibited new matter is believed to have been introduced. Amendments are made without disclaimer or prejudice to Applicants' right to pursue any canceled subject matter in a continuing application. Applicants reserve the right to file a divisional or continuation on any subject matter cancelled by way of amendment.

3. Acknowledgement of Information Disclosure Statement

Applicants note with appreciation the acknowledgement of the Information Disclosure Statement filed April 4, 2008.

4. Acceptance of the Drawings

Applicants note with appreciation the indication that the drawings submitted March 10, 2008, are deemed acceptable.

5. Acknowledgement of Certified Priority Documents

Applicants note with appreciation the indication that the certified priority documents have been received in the present application.

6. Rejection of the Claims Under 35 U.S.C. § 102(b).

Claims 1, 4, 21, 24 and 26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Vincent et al, "Variations in the fatty acid composition of zeaxanthin and astaxanthin monoesters in the ovary and hepatopancreas of the *Penaeus Schmitti* during ovogenesis," *Archives Internationales de Physiologie et de Biochimie* 97: 71-78 (1989), with English-language translation (hereinafter "*Vincent*"). The Office alleges that *Vincent* discloses an astaxanthin monoester of lauric acid (C12:0) in the ovary of *P. schmitti* during ovarian maturation in an amount of 0.9%.

Applicants traverse the rejection. The rejection is improper, at least because the cited art does not teach every element of the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

Claims 1 and 21 each recite "wherein the medium-chain fatty acid has 8 to 10 carbon atoms." *Vincent* fails to disclose at least that limitation. *Vincent* discloses individual variations in fatty acids linked to astaxanthins in monoester form in the ovary of *P. schmitti* during ovarian maturation. The fatty acids found in *Vincent* included a small percentage of lauric acid (C12:0), larger percentages of longer-chain fatty acids, and no fatty acids with less than 12 carbon atoms. For at least this reason *Vincent* fails to anticipate claims 1 and 21.

Dependent claims 4-5, 15-18, 24-26, 36 and 37, which depend from claims 1 and 21 respectively, are also not anticipated for at least the same reasons as for claims 1 and 21. For at least these reasons, no *prima facie* case of anticipation has been adduced, and the rejection should be withdrawn.

New claims 33-35 are not anticipated by *Vincent* for at least the additional reason that *Vincent* fails to disclose a food composition, cosmetic, or animal feed comprising "astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms."

7. Rejection of the Claims Under 35 U.S.C. § 103(a)

A. Obviousness of claims 21 and 15-18 over *Vincent* in view of *Hirschberg*

Claims 21 and 15-18 stand rejected under 35 U.S.C. § 103(b) as being unpatentable over *Vincent* in view of U. S. Pat. No. 5,965,795 to Hirschberg et al. (hereinafter "*Hirschberg*"). The Office alleges that *Hirschberg* teaches that it is known to use astaxanthin in a mixture for feed, coloring for the food industry and cosmetics industry and a food additive for humans. The Office concludes that because *Vincent* allegedly teaches the astaxanthin medium-chain fatty acid ester and *Hirschberg* teaches that astaxanthin is used in compositions of feed, food, and cosmetics, it would be obvious to substitute the ester of *Vincent* for the astaxanthin of *Hirschberg*.

Whether a claim is obvious is based on an objective analysis of the scope and content of the prior art, the differences between the prior art and each element of the claimed invention, and the level of skill in the pertinent art. *See Graham v. John Deere Co.*, 383 U.S. 1, 15-17 (1966). The Office's objective analysis of obviousness should be made explicit. *See KSR Int'l Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").

Hirschberg at least fails to disclose astaxanthin as an ester, much less an ester formed by linking with a medium-chain fatty acid. Therefore, *Hirschberg* fails to disclose all the limitations in claim 21, at least including that "a composition comprising at least 0.1% of astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid has 8 to 10 carbons." *Hirschberg* does not cure at least that deficiency of *Vincent*, and thus the rejection is improper.

Further, the Office has not articulated reasoning to support the legal conclusion of obviousness. *Hirschberg* teaches adding free astaxanthin. *Hirschberg* fails to disclose any astaxanthin ester much less an astaxanthin medium-chain fatty acid ester. Therefore, *Hirschberg* does not teach or suggest adding astaxanthin esters to compositions of feed, food, and cosmetics. *Hirschberg* at most teaches adding free astaxanthin to compositions of feed, food, and cosmetics. The Office provides no reasoning to support a conclusion that it would be obvious to add the astaxanthin ester of *Vincent* to a feed, food, or cosmetic.

Dependent claims 15-18 and 24-26, which depend from claim 21, are also not obvious for at least the same reasons as for claims 1 and 21. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

New claims 33-35 are not obvious over *Vincent* in view of *Hirschberg* for at least the additional reason that both *Vincent* and *Hirschberg* fail to disclose a food composition, cosmetic, or animal feed comprising “an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms.”

B. Obviousness of claims 1, 4, 5, 7, 15-18, 21, 24-27, and 29-32 over *Asami*

Claims 1, 4, 5, 7, 15-18, 21, 24-27, and 29-32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U. S. Pat. No. 6,265,450 to *Asami et al* (hereinafter “*Asami*”). The Office alleges that *Asami* discloses astaxanthin saturated fatty acid monoesters. The Office further alleges that *Asami* teaches that any monoester of a saturated fatty acid is operable in the composition of *Asami*. The Office concludes that it would be obvious from the teachings of *Asami* to form astaxanthin saturated fatty acid monoesters including any medium-chain fatty acid with 8 to 12 carbon atoms.

Applicants traverse this rejection. Whether a claim is obvious is based on an objective analysis of the scope and content of the prior art, the differences between the prior art and each element of the claimed invention, and the level of skill in the pertinent art. See *Graham v. John Deere Co.*, 383 U.S. 1, 15-17 (1966). The Office’s objective analysis of obviousness should be made explicit. See *KSR Int’l Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007); *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]jections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

1. No articulated reasoning to support obviousness conclusion

The Office fails to provide any evidence to support the legal conclusion that *Asami* teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success. *Asami* only particularly teaches long-chain fatty acids having at least 16 carbon atoms. See, e.g., *Asami* col. 6, ll. 30-34. Thus, the guidance provided by *Asami* is to use long-chain fatty acids. The Office provides no suggestion or

rationale for why it would be obvious to one having ordinary skill in the art at the time Applicants' invention was made to use medium-chain fatty acids in forming the astaxanthin fatty acid ester.

No evidence provided on the record suggests using medium-chain fatty acids outside of the Applicant's own disclosure. Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). It is clear based on *Asami* that a person of ordinary skill in the art only contemplated long-chain fatty acids for esterification of astaxanthin. This is buttressed by the background section of the Specification. Astaxanthin fatty acid esters found in nature and contemplated by people of ordinary skill in the art were generally present in a mixture of long-chain fatty acids (i.e. palmitic acid, stearic acid, etc. as described in *Asami*). *See, e.g.*, Specification p. 3, ll. 1-6. Also, the described prior processes of esterifying astaxanthin included only long-chain fatty acids. *See, e.g.*, Specification p. 3, ll. 6-22. Therefore, based on both the art described by Applicant and *Asami*, it is obvious that one of ordinary skill in the art at the time of Applicant's invention did not contemplate astaxanthin medium-chain fatty acid esters. Therefore, the Office is impermissibly relying on Applicant's own disclosure for a suggestion to use medium-chain fatty acids. Thus, for at least these reasons no *prima facie* case of obviousness has been adduced, and Applicants respectfully request withdrawal of the rejection.

2. Claimed species is not obvious over cited genus

The Office appears to be arguing that the claimed invention is obvious because *Asami* teaches a genus that encompasses the claimed species or subgenus. The fact that a claimed compound may be encompassed by a disclosed generic description does not by itself render that compound obvious. *In re Jones*, 958 F.2d 347, 350, 21 U.S.P.Q.2d 1941, 1943 (Fed. Cir. 1992). *See also* MPEP § 2144.08(II). The Office has developed guidelines on how to follow the obviousness factors set out by the Supreme Court in genus/species situations. *See* MPEP § 2144.08. When these are properly applied it is clear there is no suggestion to select the particularly claimed medium-chain fatty acids from the generic disclosure of saturated fatty acids in *Asami*.

Applicants agree with the Office that *Asami* fails to disclose that the astaxanthin monoester includes a medium-chain fatty acid with 8 to 12 carbon atoms. However, the Office mischaracterizes *Asami*. *Asami* does not teach or suggest that any monoester of a

saturated fatty acid works in the composition of *Asami*. *Asami* only states that “in the present invention, esters of astaxanthin include monoesters or diesters of saturated fatty acids such as palmitic acid and stearic acid.” See, e.g., *Asami* col. 6, ll. 28-30. This statement reasonably provides that palmitic acid and stearic acid are contemplated for use in the composition of *Asami*. When reading “saturated fatty acid” in context with the specific fatty acids described, *Asami* is clearly using the term merely to differentiate from unsaturated fatty acids. *Asami* is not using the term to incorporate each and every saturated fatty acid in the invention. Instead, one of ordinary skill in the art would recognize that *Asami* only contemplates long-chain fatty acids (i.e. 16 carbons or greater) and the term “saturated fatty acids” is referring to saturated long-chain fatty acids.

The scope and content of *Asami* includes esters of astaxanthin formed by esterification with fatty acids and says that both saturated fatty acids or unsaturated fatty acids can be used. See, e.g., *Asami* col. 6, ll. 28-34. *Asami* teaches that it is preferred to use unsaturated fatty acids because they create an astaxanthin ester that is more stable. See, e.g., *Asami* col. 6, ll. 34-40. All of the expressly described species are long-chain fatty acids containing at least 16 carbon atoms. See, e.g., *Asami* col. 6, ll. 28-34. Although *Asami* recites saturated fatty acids and unsaturated fatty acids generically, based on the expressly described species for both, it is clear *Asami* did not contemplate the use of medium-chain fatty acids. Further, “unsaturated” and “saturated” are being used in *Asami* to differentiate two lists of long-chain fatty acids, not to describe generically every known fatty acid. Therefore, the disclosure of *Asami* suggests a preference for astaxanthin esters containing long-chain unsaturated fatty acids and that any contemplated saturated fatty acids are long-chain fatty acids.

The differences between the scope of *Asami* and the scope of the claimed invention are substantial. The closest described fatty acids are palmitic acid with 16 carbon atoms in *Asami* compared to a fatty acid containing 10 carbon atoms in the claimed invention. Applicants have discovered that astaxanthin medium-chain fatty acid esters, which include fatty acids with substantially less than 16 carbon atoms, improve intestinal absorption rates. See, e.g., Specification p. 5, l. 17 – p. 6, l. 12. For example, Applicants’ Figures 1 and 2 show the superior digestibility of C8 fatty acid monoesters compared to C8 fatty acid diesters and Astax9000H manufactured by Itano, which is an extracted naturally occurring mixture of astaxanthin esters. See, e.g., Specification p. 4, l. 24 – p. 5, l. 10 and Figs. 1 and 2.

Further, Applicants made it possible to produce the medium-chain fatty acid ester. Prior methods of forming astaxanthin fatty acid esters formed astaxanthin diesters having both long-chain and medium-chain fatty acids, and when medium-chain fatty acids were used instead of a long chain fatty acid, esterification was not sufficiently carried out. *See, e.g.*, Specification p. 11, ll. 4-10. In contrast, Applicants discovered that by adding several percent of water to the reaction system, esters are sufficiently formed from astaxanthin and medium chain fatty acids. *See, e.g.*, Specification p. 11, ll. 10-15. Therefore, one of ordinary skill in the art would not find it obvious to form astaxanthin medium-chain fatty acids or extract the same from nature without Applicants' disclosure, because the state of the art at the time of Applicants' invention was that sufficient esterification was not possible with astaxanthin and medium-chain fatty acids. Thus, the rejection is improper for at least the reason that sufficient formation of astaxanthin medium-chain fatty acid monoesters would not be expected.

Finally, there must be some motivation to select the claimed species or subgenus. *See* MPEP § 2144.08(A)(4). However, *Asami* and the cited art of record in Applicants' Specification expressly teach that naturally occurring and synthetically created astaxanthin fatty acid esters prior to Applicants' invention were formed with long-chain fatty acids. Further, one of ordinary skill in the art at the time of Applicants' invention only contemplated esterifying astaxanthin with long-chain fatty acids. Therefore, one of ordinary skill in the art would not, without some express motivation, create medium-chain fatty acid esters of astaxanthin. However, the Office provides no motivation. Thus, for at least these reasons no *prima facie* case of obviousness has been adduced, and Applicants respectfully request withdrawal of the rejection.

3. Objective evidence showing unobviousness must be considered

Irrespective of whether the Office has established a *prima facie* case of obviousness, Applicants have further included evidence of unobviousness in the specification as originally filed. Secondary considerations, such as unexpected results, failure of others, etc., which are indicia of non-obviousness must be taken into account, if present. *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 894, 904 (Fed. Cir. 1988). Applicants unexpectedly discovered that astaxanthin medium-chain fatty acid esters improve intestinal absorption rates of the astaxanthin. *See, e.g.*, Specification p. 5, l. 17 – p. 6, l. 12. This unexpected improvement is demonstrated by the comparison of Examples 1-2 containing the formation and reaction of an

astaxanthin with octanoic acid (C8) and tricaprilin (C10) respectively to Examples 3-4 containing astaxanthin oleic acid ester. *See, e.g.*, Specification p. 32, l. 19 – p. 35, l. 1. After 3 days of enzyme reaction the composition ratio of astaxanthin was at least about 85% for Examples 1-2 and less than about 73% for Examples 3-4. *See, e.g.*, Specification p. 32, l. 19 – p. 35, l. 1.

Asami is silent to using medium-chain fatty acids and instead prefers long-chain fatty acids. *Asami* further fails to contemplate Applicants' newly discovered advantage in absorption rates created by use of medium-chain fatty acids as opposed to conventional long-chain fatty acids. Therefore, for at least the above reasons claims 1, 7, 21, and 27 are not obvious over *Asami*.

Dependent claims 4-5, 15-18, 24-26 29-32, 36, and 37, which depend from claims 1, 21, and 27 respectively, are also not obvious for at least the same reasons as for claims 1, 21, and 27. For at least these reasons, the rejection should be withdrawn.

New claims 33-35 are not obvious over *Asami* for at least the additional reason that *Asami* fails to disclose a food composition, cosmetic, or animal feed comprising "an astaxanthin medium-chain fatty acid ester, wherein the medium-chain fatty acid ester is a monoester, and wherein the medium-chain fatty acid has 8 to 10 carbon atoms."

8. Response to Restriction

Applicants maintain their request for claims 8-14, 19-20, and 28 to be rejoined and considered on the merits. The restriction is predicated on claims 1 and 21 being rejected by *Vincent* or *Asami*. However, because neither *Vincent* nor *Asami* teach the special technical feature for at least the reasons presented above, the restriction requirement should be withdrawn. Accordingly, Applicants request that all the withdrawn claims be rejoined and examined on the merits.

CONCLUSION

Reconsideration and reexamination of the claims is respectfully requested. If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account. If any issues remain outstanding, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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